

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

*AMB*

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Certifier	<u>S. Reese</u>

[Docket No. 00N-1395]

**Agency Information Collection Activities; Proposed Collection; Comment Request;  
Medicated Feed Mill License**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension for an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information for medicated feed mill licensing requirements.

**DATES:** Submit written comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA, 44 U.S.C. 3501–3520, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Medicated Feed Mill License 21 CFR Part 515—(OMB Control Number 0910–0337)—  
Extension**

In the **Federal Register** of November 19, 1999 (64 FR 63195), FDA published a final rule implementing the feed mill licensing provisions of the Animal Drug Availability Act of 1966 (Public Law 104–250). The rule added part 515 (21 CFR part 515) to provide the requirements for medicated feed mill licensing.

The rule set forth the information to be included in a medicated feed mill license application and subsequent supplemental applications. Also, it set forth criteria for the approval and

nonapproval of a medicated feed mill license application and the criteria for the revocation and/or suspension of a license. More specifically, § 515.10(b) specifies requirements for submitting a completed medicated feed mill license application, using Form FDA 3448. Section 515.11(b) specifies requirements for supplemental medicated feed applications for a change in ownership and/or change in mailing address for the facility cite, using Form FDA 3448. Section 515.23 sets forth written requirements for voluntary revocation of a medicated feed mill license by a sponsor on the grounds that the facility no longer manufacture any animal feed. Section 515.30(c) details requirements for filing a request for a hearing by a sponsor to give reasons why a medicated feed mill license application should not be refused or revoked and § 510.305(b) (21 CFR 510.305(b)) requires maintenance of approved labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

Respondents to this collection of information are individuals or firms that manufacture medicated animal feed.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	100	1	100	0.25	25
515.11(b)	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30(c)	0.15	1	0.15	24	3.6
Total					47.10

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305(b)	100	1	100	.25	25

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate for the number of respondents is derived from agency data, i.e. the number of medicated feed manufacturers entering the market each year, change in ownership or address,

requests for voluntary revocation of a medicated feed mill license, revocation and/or suspension of a license. I ne estimate of the time required for the reporting and recordkeeping requirements is based on the agency communication with industry.

Dated: July 21, 2000



William K. Hubbard,  
Senior Associate Commissioner  
for Policy, Planning, and Legislation.

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